

nonclinical paradigm for assessing Torsade de Pointes (TdP) risk and explore the parameters for an appropriate, strong, nonclinical proarrhythmia screening method as an alternative to clinical Thorough QT studies. The workshop, which will seek input from all attendees, is intended to provide a forum for stakeholders, including experts and opinion leaders from academia, industry, and regulatory agencies in the United States, the European Union, Canada, and Asian countries, to discuss what a new framework might look like, the benefits and limitations of the current guidelines, and the importance of a uniform assay schema.

**Date and Time:** The public workshop will be held on July 23, 2013, from 8 a.m. to 6 p.m.

**Location:** The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993.

**Contact Person:** Devi Kozeli, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4183, Silver Spring, MD 20993, 301-796-1128, email: [devi.kozeli@fda.hhs.gov](mailto:devi.kozeli@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

This workshop will introduce for discussion a new nonclinical paradigm for assessing TdP risk and explore the parameters for an appropriate, strong, nonclinical proarrhythmia screening method as an alternative to clinical Thorough QT studies. The workshop, which will seek input from all attendees, is intended to provide a forum for stakeholders, including experts and opinion leaders from academia, industry, and regulatory agencies in the United States, the European Union, Canada, and Asian countries, to discuss what a new framework might look like, the benefits and limitations of the current guidelines, and the importance of a uniform assay schema.

A description of the planned activities for the workshop can be found at: <http://www.hesiglobal.org/i4a/pages/index.cfm?pageID=3620> (FDA has verified this online address but is not responsible for subsequent changes to the Web site where it is located after this document publishes in the **Federal Register**.)

**Registration and Accommodations:** Registration for non-FDA attendees should be performed online at the following address: [https://evm.auxserv.duke.edu/iebms/reg/reg\\_p1\\_form.aspx?](https://evm.auxserv.duke.edu/iebms/reg/reg_p1_form.aspx?oc=10&ct=DCRIHBD09&eventid=50715)

[oc=10&ct=DCRIHBD09&eventid=50715](https://evm.auxserv.duke.edu/iebms/reg/reg_p1_form.aspx?oc=10&ct=DCRIHBD09&eventid=50715). (FDA has verified this online address but is not responsible for subsequent changes to the Web site where it is located after this document publishes in the **Federal Register**.)

Registration for FDA attendees is also online, at the following address: [https://duke.qualtrics.com/SE/?SID=SV\\_bmv7T8GPm4IAPd3](https://duke.qualtrics.com/SE/?SID=SV_bmv7T8GPm4IAPd3).

The registration deadline for paying attendees is July 15, 2013. With the exception of FDA employees and a limited number of speakers or organizers, registrants must pay a registration fee covering the cost of facilities, materials, and food. The registration fees for different categories of attendee are as follows:

Category	Cost
Commercial Entity or Industry, Not Members of HESI .....	\$950
Commercial Entity or Industry, HESI Members .....	600
Academia, Professional Society, or Nonprofit Organization .....	250
Government (non-FDA) .....	150

Seats are limited, and conference space will be filled in the order in which registrations are received.

Attendees are responsible for their own accommodations.

If you need special accommodations due to a disability, please contact Devi Kozeli (see *Contact Person*) at least 7 days in advance.

Dated: June 12, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Proposed Collection; 60-Day Comment Request; Awareness and Beliefs About Cancer Survey, National Cancer Institute (NCI)**

**Summary:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**To Submit Comments and for Further Information:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Sarah Kobrin, Division of Cancer Control and Population Sciences, 9609 Medical Center Dr., MSC 9761, Rockville, MD 20852, or call non-toll-free number 240-276-6931 or Email your request, including your address to: [kobrin@mail.nih.gov](mailto:kobrin@mail.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

**Comment Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

**Proposed Collection:** Awareness and Beliefs about Cancer Survey, 0925-NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

#### **Need and Use of Information**

**Collection:** The objective of the study is gather data about American adults' awareness and beliefs about cancer. The ultimate goal is to determine how individuals' perceptions of cancer may influence their decisions to report signs and symptoms to health care providers, perhaps affecting the disease stage of diagnosis and the effectiveness of treatment. Data will be collected from approximately 2,000 adults aged 50 years or older across the United States for the NCI Awareness and Beliefs about Cancer survey over a one-year period.

OMB approval is requested for one year. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,334.

## ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Screener .....	Adults 50+ years old .....	8,000	1	5/60	667
Survey .....	General Public .....	2,000	1	20/60	667

Dated: June 11, 2013.

**Vivian Horovitch-Kelley,**

*NCI Project Clearance Liaison, National Institutes of Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Arthritis, Bone and Skeletal Biology.

*Date:* July 12, 2013.

*Time:* 2:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

*Contact Person:* Aruna K Behera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301-435-6809, [beheraak@csr.nih.gov](mailto:beheraak@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Biochemistry & Macromolecular Biophysics.

*Date:* July 15-17, 2013.

*Time:* 8:00 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* James W Mack, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4154, MSC 7806, Bethesda, MD 20892, (301) 435-2037, [mackj2@csr.nih.gov](mailto:mackj2@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel Fellowship: Physiology and Pathobiology of Musculoskeletal, Oral, and Skin Systems.

*Date:* July 15, 2013.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Anshumali Chaudhari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802, Bethesda, MD 20892, (301) 435-1210, [chaudhaa@csr.nih.gov](mailto:chaudhaa@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowships: Chemistry, Biochemistry and Biophysics.

*Date:* July 17-18, 2013.

*Time:* 8:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Michael Eissenstat, Ph.D., Scientific Review Officer, BCMB IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4166, MSC 7806, Bethesda, MD 20892, 301-435-1722, [eissenstatma@csr.nih.gov](mailto:eissenstatma@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR-13-008: Shared Instrumentation: X-ray.

*Date:* July 17, 2013.

*Time:* 1:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* William A. Greenberg, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4168, MSC 7806, Bethesda, MD 20892, (301) 435-1726, [greenbergwa@csr.nih.gov](mailto:greenbergwa@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 13, 2013.

**Carolyn A. Baum,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; NIAMS Small Grant Program for New Investigators (R03).

*Date:* July 11-12, 2013.

*Time:* 9:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, One Democracy Plaza, Suite 800, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Kan Ma, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, NIH, 6701 Democracy Boulevard, Suite 800, Bethesda, MD 20892, 301-451-4838, [mak2@mail.nih.gov](mailto:mak2@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)